REMARKS

I. The Office Action

The Office acknowledged that the Information Disclosure Statement of May 5, 2008, has been considered. The Office requested that Applicants review the specification for the trademark TWEEN®. Applicants amended the specification at page 11 to properly recognize the trademark and to include generic terminology.

The Office maintained the rejection of claim 13 under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description. Claims 1-3, 5-12, 19, 21-23, and 26-30 were rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable in view of West et al., *Sex Transm. Inf.*, *78*, 282-285 (2002) ("the West reference") taken in view of Egglestone et al., *Communicable Dis. Pub. Health*, *3*, 158-162 (2000) ("the Egglestone reference") and/or Zarakolu et al., *J. Clin. Microbiol.*, *40*, 3064-3065 (2002) ("the Zarakolu reference") taken in view of Sambri et al., *Clin. Diag. Lab. Immunol.*, *8*, 534-539 (2001) ("the Sambri reference"). The Office rejected claim 21 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for lacking antecedent basis. Reconsideration of the rejections is hereby requested.

II. The Claim Amendments and Pending Claims

Claim 3 has been amended to correct a typographical error. Claim 13 has been amended to recite that VDRL antigen is present at different positions on the carrier such that anti-VDRL-IgG and anti-VDRL-IgM antibodies can be differentiated after reaction with a patient's sample, as supported by the specification at, e.g., page 4, paragraphs 3 and 5; the paragraph bridging pages 5 and 6; page 7, paragraph 1; page 8, paragraph 6, through page 9, paragraph 4; and Figures 4 and 5. Claim 21 has been amended to correct a matter of form. Claim 24 has been amended to correct a grammatical error. Claims 31-35 are new and directed to the elected invention. New claims 31-35 are supported by the specification at, e.g., page 3, paragraph 4; page 4, paragraphs 3-5; and page 5, paragraphs 1, 3, and 5. No new matter has been added by way of these claim amendments or additions.

Claims 1-35 are pending, and claims 4, 14-18, 20, 24, and 25 have been withdrawn from consideration for allegedly being directed to a non-elected invention. Pending claims 1-3, 5-13, 19, 21-23, and 26-35 are under examination insofar as the claims are directed to a carrier for diagnosis and/or follow-up of a *Treponema* infection, the carrier comprising (i) at least one immobilized cardiolipin and (ii) the *Treponema pallidum*-specific 47 kD antigen.

III. The Rejection under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn.

The Office maintained the rejection of claim 13 under Section 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that Applicants had possession of the invention at the time the application was filed. The rejection is respectfully traversed for the reasons set forth below.

According to the Office, claim 13 lacks adequate written description because the specification does not describe an antigen that allows differentiation between IgG and IgM antibodies in a sample. (Office Action, page 6.) Claim 13 has been amended to recite that the Venereal Disease Research Laboratory (VDRL) antigen is present at *different positions* on the carrier such that anti-VDRL-IgG and anti-VDRL-IgM antibodies can be differentiated after reaction with a patient's sample. For example, when the carrier is a test strip, the multiple bands of VDRL antigen is present at different positions such that IgG reactivity can be detected at one position, while IgM reactivity can be detected at a separate position. The application describes the subject matter of claim 13 so as to satisfy the requirements of Section 112, first paragraph. The specification describes a carrier comprising multiple VDRL and/or Treponema-specific antigen bands (see, e.g., page 4, paragraphs 3 and 5, and Figures 4 and 5). The positioning of the bands allows a practitioner to differentiate IgM-antigen binding from IgG-antigen binding upon development of the carrier. For example, as described in the specification at the paragraph bridging pages 5 and 6, the intensities of a VDRL-IgG band (i.e., one of the multiple VDRL bands which is developed using anti-IgG), a VDRL-IgM band (i.e., one of the multiple VDRL bands which is developed using anti-IgM), and a Treponema-specific antigen band are compared with the intensity of a control band, which also is situated on the carrier (see, e.g., paragraph bridging

pages 5 and 6). Immobilization of the antigen at multiple positions allows separate detection of different antibody reactivities in analytical material (see specification at, e.g., page 9, paragraph 3). The specification conveys with reasonable clarity to those skilled in the art that Applicants possessed the subject matter of claim 13 as of the filing of the application, thereby satisfying the written description requirement of Section 112. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

IV. The Rejection under 35 U.S.C. § 103(a) Should Be Withdrawn.

Claims 1, 2, 5, 6, 10, 11, 19, 21, and 26 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of the West reference taken with the Egglestone reference. Claims 1-3, 5-12, 19, 21-23, and 26-30 were rejected under Section 103(a) as allegedly being obvious in view of the Zarakolu reference taken with the Sambri reference. The obviousness rejection in this case cannot stand because the Office has not supported the assumptions upon which the rejection is based with evidence, and the stated reason for combining the teachings of the cited references is not rational. As part of the response to the Office action, Applicants have submitted herewith a Declaration under 37 C.F.R. § 1.132 of Martin Kintrup, Ph.D., a co-inventor of the instant application and scientist whose long experience in the field qualifies him to comment on what one of ordinary skill in the art would have understood and predicted from the cited art in 2002. (See Rule 132 Declaration at paragraphs 1-4.)

According to the Office, the West reference purportedly discloses the RPR test and the RST assay for syphilis diagnosis. The Office asserts that the RPR test is an agglutination test wherein VDRL antigen is immobilized on carbon particles, which serve as a "carrier." (Applicants maintain for the reasons of record that carbon particles present in the RPR assay are not "carriers.") The RST assay allegedly is an immunochromatographic strip test that contains the 47 kD *Treponema pallidum* antigen immobilized on a test strip. The Office acknowledged that the West reference fails to disclose (a) a single carrier comprising both immobilized VDRL antigen (i.e., the cardiolipin antigen) and immobilized 47 kD antigen; (b) a carrier made of nitrocellulose, PVDF, nylon, cellulose, acetate, or polystyrene; or (c) a test kit including instructions. West also does not teach applying cardiolipin at various concentrations on a carrier. The Egglestone reference purportedly cures the

deficiencies in the West reference by suggesting employing a quantitative non-Treponemal test and a Treponemal immunoassay in syphilis diagnosis. The Zarakolu reference purportedly discloses an immunochromatographic test strip comprising the *Treponema pallidum* 47 kD antigen and a band of anti-human IgG. The Zarakolu reference also allegedly mentions that syphilis testing generally includes non-Treponemal tests and tests for Treponemal antigens. The Zarakolu reference does not teach (a) a carrier comprising both a cardiolipin antigen and the 47 kD antigen, (b) application of cardiolipin at varying concentrations on the carrier, (c) an immunoblot design, or (d) a test kit further comprising instructions. The Sambri reference allegedly cures the deficiencies of the Zarakolu reference by disclosing a Western blot test wherein test strips comprise different Treponemal antigens on the strip.

The references do not teach or suggest a single carrier comprising *both* immobilized VDRL antigen *and* immobilized 47 kD antigen. Nevertheless, the Office alleges that it would have been obvious to use the VDRL antigen on the immunochromatographic test strip disclosed in the West reference because the Egglestone reference recommends using both tests to diagnosis syphilis. Likewise, the Office contends that it would be obvious to use the VDRL antigen on the Zarakolu reference's test strip because of "ease of use and because both tests are generally used in the diagnosis of syphilis." According to the Office, one of ordinary skill purportedly would have had a reasonable expectation of success because "immunochromatographic tests performed using test strips are commonly used in the art with numerous different antigens" and "immunoassays using VDRL antigen and the 47 kD treponemal antigen have been shown to be successful" by the West reference and the Zarakolu reference. (Office Action, pages 11 and 15.) The "successful" immunoassays referenced by the Office do not use "VDRL antigen and the 47 kD treponemal antigen." Instead, the assays comprise *either* the VDRL antigen *or* a treponemal antigen; the references do not suggest that combining the two antigens in a single assay is possible.

While an explicit teaching, suggestion, or motivation is not needed to combine the teachings of prior art references, the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007) held that an obviousness rejection "cannot be sustained by mere

conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." The Patent Office's "Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 In View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.," 72 Fed. Reg. 57526 (October 10, 2007) sets forth seven rationales that can support a conclusion of obviousness. As explained below, the rationales all require either a finding that the results of the combination or substitution would be predictable, or a finding of motivation to solve a problem with a reasonable expectation of success, neither of which is present here.

(A) *Combining prior art elements according to known methods to yield predictable results*. This rationale requires a finding that one of ordinary skill would have recognized that the results of the combination of individual elements were predictable. The Office failed to support its factual assumptions in this regard with cited evidence. M.P.E.P. § 2144.03 states that:

> It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, ***assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art***. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 U.S.P.Q. 57, 63 (CCPA 1979) ("[W]hen the PTO seeks to rely upon a chemical theory, in establishing a prima facie case of obviousness, it must provide evidentiary support for the existence and meaning of that theory.") [Emphasis added.]

The pending claims are directed to a carrier for diagnosis and/or follow-up of a *Treponema* infection. The carrier comprises at least one immobilized cardiolipin (e.g., in the form of VDRL antigen) and at least one immobilized *Treponema*-specific antigen (e.g., the 47 kD *Treponema pallidum* antigen). As explained by Dr. Kintrup, multiple reactions are required to prepare a carrier for diagnosis and/or follow-up of a *Treponema* infection. (Rule 132 Declaration, paragraphs 5 and 6.) After applying antigen to a carrier, free binding sites must be blocked to reduce non-specific binding of serum components to the carrier.

Otherwise, high background reactions influence the final test result, and the carrier is not suitable for diagnosing infection. In addition, the antigen must remain immobilized and retain its antigenic structure to allow capture of antibodies indicative of infection. If the antigens are solubilized or structurally changed, the carrier is not suitable for diagnosing infection. (See Rule 132 Declaration, paragraph 6.)

Applicants do not dispute that immunoassays using VDRL antigen and *separate* immunoassays comprising the 47 kD *Treponema* antigen have been successful in identifying syphilis. With respect to an immunoassay that *combines* VDRL and *Treponema* proteins, however, the Office has *not shown* that one of ordinary skill in the art *would have predicted* that a single carrier could be produced that comprises both antigens and detects anti-VDRL antibodies and anti-*Treponema* antibodies with the sensitivity required to diagnose infection. The chemical nature of cardiolipin and *Treponema* proteins are fundamentally different. Cardiolipin lipids are small hydrophobic molecules, while *Treponema* protein antigens are larger molecules that are hydrophilic under most conditions. (See Rule 132 Declaration, paragraph 7.) Prior to the invention, one of ordinary skill would have believed the two different antigens to be incompatible for a single immunoassay. For example, detergents are commonly used to reduce unspecific binding to protein antigens and carrier material, thereby increasing assay sensitivity to the level required for infection diagnosis. (See, for example, the Sambri reference at page 536, column 2, paragraphs 1 and 2.) Lipids, however, are generally solubilized by detergents and released from the carrier surface, i.e., the lipid antigen is not immobilized on the carrier. See, e.g., International Patent Publication WO 91/10138, cited by the Office as disclosing binding of cardiolipin to a support. WO 91/10138 teaches that detergents cannot be used with enzyme-linked immunosorbent assays (ELISAs) employing cardiolipin. As a result, cardiolipin ELISA assays are not very specific or sensitive. (See Rule 132 Declaration, paragraph 7.) Initial attempts by the Applicants to produce the "one-test system," using the detergent concentration disclosed in the Sambri reference, resulted in release of cardiolipin from the carrier (i.e., the cardiolipin was not immobilized). (See Rule 132 Declaration, paragraph 8.) To allow use of detergents to increase specificity, WO 91/10138 proposes elaborate techniques for immobilizing lipids to increase resistance to detergents; however, the proposed methods for adhering cardiolipin to a carrier are incompatible with protein antigens and

certain carrier materials, e.g., nitrocellulose. For example, a preferred coupling method disclosed in WO 91/10138 requires oxidation reagents that would disrupt all or part of protein antigenic epitopes comprising amino acids sensitive to oxidation. WO 91/10138 also teaches non-covalent passive adsorption of lipids onto a carrier, which is not suitable for, e.g., nitrocellulose. (See Rule 132 Declaration, paragraph 9.) Likewise, the ethanol-based method of immobilizing cardiolipin on a support disclosed in Pedersen et al. *J. Clin. Microbiol.*, *25*(9): 1711-1716 (1987) (cited in the Office Action at page 9) is not suitable for use in conjunction with protein antigens and, e.g., nitrocellulose. Exposure to ethanol precipitates protein antigens, rendering a carrier comprising both cardiolipin and a *Treponema*-specific antigen unable to detect anti-*Treponema* antibodies. (See Rule 132 Declaration, paragraph 10.) Moreover, nitrocellulose membranes are damaged with ethanol and other organic solvents. (See Rule 132 Declaration, paragraph 9.) One of ordinary skill would not have predicted that a single carrier could contain both protein antigens and lipid antigens *and* remain suitable for detecting *Treponema* infection.

Indeed, it was only after extensive experimentation that Applicants successfully generated a carrier comprising both immobilized cardiolipin and a *Treponema*-specific antigen. The interplay between lipid antigen, protein antigen, and buffer used to block free binding sites on the carrier influences the sensitivity and specificity of the *Treponema* test. Low detergent concentrations resulted in high, unspecific background reaction of the protein antigens. Higher detergent concentrations, required to correct background with respect to the protein antigen, solubilized lipid antigens from the carrier, resulting in insensitive detection of anti-lipid antibodies. Initial experiments employing the detergent concentration disclosed in the Sambri reference failed to produce a carrier comprising both immobilized cardiolipin and immobilized *Treponema*-specific antigen. (Rule 132 Declaration, paragraph 8.) The applicants surprisingly discovered that cardiolipin antigen reactivity could be maintained at a level required for a diagnostic test while maintaining sensitive and selective reactivity of *Treponema* protein antigens to anti-*Treponema* antibodies on the same carrier. (See Rule 132 Declaration, paragraph 12.) One of ordinary skill would not have predicted such an assay could be generated prior to the claimed invention.

The Office disregarded Applicants' assertion in the Amendment dated May 5, 2008, that immobilizing cardiolipin on carrier while retaining reactivity is not trivial, citing a lack of objective evidence and stating that "[t]he specification and the breadth of the claims suggest the opposite of what application is arguing. The claims do not require any special treatment or conditions for the antigens to be bound to the carrier and the specification does not mention any difficulties on of skill in the art might encounter." (Office Action, pages 8 and 9; see also page 13.) First, the claims are directed to a product, and need not recite conditions required to generate the product. Second, a specification need not disclose difficulties encountered in reducing an invention to practice to rebut an obviousness rejection. See 72 Fed. Reg. at 57527 ("Objective evidence relevant to the issue of obviousness must be evaluated . . . The evidence may be included in the specification as filed . . . or be provided in a timely manner at some other point during the prosecution."). The Rule 132 declaration submitted herewith provides additional objective evidence which rebuts the Office's allegation of obviousness.

In support of its obviousness rejection, the Office proposed that one of ordinary skill would have had a reasonable expectation of success because "immunochromatographic tests performed using test strips are commonly used in the art with numerous different antigens," citing the Sambri reference in support of its assumption. However, the Sambri reference discloses testing strips comprising multiple *Treponema* protein antigens, prepared using methods that solubilize cardiolipin. (See Rule 132 Declaration, paragraphs 7 and 8.) Indeed, adhering multiple proteins to a carrier does not entail the same technical hurdles as generating a single carrier suitable for diagnosing *Treponema* infection and comprising both *Treponema*-specific antigen and cardiolipin, which have fundamentally distinct chemical properties. (See Rule 132 Declaration, paragraphs 7-10.)

The Office also alleged that one would have had a reasonable expectation of success because "immunoassays using VDRL antigen and the 47 kD treponemal antigen have been shown to be successful," citing the West and Zarakolu references. (Office Action, pages 11 and 15.) The references only establish that separate assays that use divergent assay materials and assay conditions could be successful. A person of ordinary skill in the field

would have appreciated the importance of the divergent assay set-up. Indeed, reagents used in typical VDRL antigen-based assays cannot be used with protein antigens or certain carrier materials. (See Rule 132 Declaration, paragraph 11.) For the scientific reasons set forth above, one would not have predicted that the VDRL antigen and the 47 kD treponemal antigen could be *combined* on a single, functional carrier. The evidence of success using *separate* protein- and lipid-based assays did not suggest a solution to overcome the problem of how to assay these divergent types of antigens together on a single carrier. The Office has not cited any evidence to the contrary; therefore, a conclusion of obviousness cannot be sustained.

(B) *Simple substitution of one known element for another to obtain predictable results*. This rationale requires a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable. For the reasons stated above in section A, cardiolipin has different properties from *Treponema* protein antigens, and cardiolipin is not readily substitutable for protein-based antigens. Moreover, for the reasons stated above in section A, the Office has not cited to any evidence to support a factual assumption that the results of any substitution would have been predictable.

(C) *Use of a known technique to improve similar products in the same way*. This rationale requires a finding that the prior art contained a "comparable" device that was improved in the same way as the claimed invention, and that the results of applying the "improvement" technique would have been predictable. For the reasons stated above in section A, a single carrier comprising both immobilized cardiolipin and immobilized *Treponema*-specific antigen (e.g., the 47 kD *Treponema* antigen) is not comparable to carriers comprising multiple protein antigens or separate carriers comprising protein or lipid. Moreover, for the reasons stated above in section A, the Office has not cited to any evidence to support a factual assumption that the results would have been predictable.

(D) *Applying a known technique to a known device ready for improvement to yield predictable results*. This rationale requires a finding that one of ordinary skill in the art would have recognized that applying the known technique would yield predictable results and result in an improved product. Applicants dispute that existing non-*Treponema* and

Treponema-specific assays were "ready for improvement." The Egglestone reference cited by the Office, for example, suggests performing *multiple, separate* assays, i.e., primarily screening for *Treponema* antibodies and *later* confirming infection via a VDRL test. There was no obvious need to improve existing VDRL or *Treponema*-specific assays. Moreover, for the reasons stated above in section A, the Office has not cited any evidence to support a factual assumption that immobilizing cardiolipin and the 47 kD *Treponema* antigen on a single carrier would *predictably* result in a functional, much less *improved*, product.

(E) *"Obvious to try" – choosing from a finite number of identifiable solutions to a problem.* This rationale requires a finding that there was a recognized problem or need in the art. The Office has not provided any evidence to support the factual assumption that there was a recognized problem or need with respect to existing non-Treponemal and Treponemal tests. While the Office suggests in paragraph 3 on page 11 of the Action that the Egglestone reference's purported recommendation to use both Treponemal and non-*Treponema* assays during diagnosis is motivation, the Office has not pointed to any evidence that the existing *Treponema* and non-*Treponema* assays were suboptimal and thus needed modification.

A finding of obviousness under the "obvious to try" rationale also requires a finding of a finite number of predictable potential solutions and a reasonable expectation of success in pursuing these potential solutions. The Office failed to establish that one of ordinary skill would consider combining two fundamentally different antigen types, i.e., the 47 kD *Treponema* antigen and cardiolipin, on a single carrier as a potential solution. As established above, even if the need to run separate assays were "a recognized problem," the biochemistry resulted in separate assays and there were not a finite number of identifiable solutions in the art. The Office (not any of the cited references) proposed combining two tests into one for "ease of use," but ignored the basic differences between *Treponema*-specific and non-*Treponema* assays that lead *away* from combining the antigens in a single assay. In essence, the Office has identified one of the features of the invention, re-characterized the feature as a recognized problem, and assumed that routine selection of one assay format would operate as a solution. The VDRL- and 47 kD *Treponema* antigen-based assays described in the cited art require different test procedures, different storage, and different

conservation substances. In fact, some reagents typically employed in VDRL antigen-based assays cannot be used with protein antigens or certain carrier material. Ethanol and formaldehyde, for example, precipitate protein, disrupt antigenic epitopes, and/or destroy carrier material, such as nitrocellulose. (See Rule 132 Declaration, paragraphs 10 and 11.) In addition, the manufacturer of nitrocellulose membranes had no specific data on immobilizing lipids to nitrocellulose around the effective filing date of the instant application. (Rule 132 Declaration at paragraph 9.) Moreover, for the reasons discussed above in section A, the Office has not provided any evidence to support a factual assumption of predictability and reasonable expectation of success.

(F) *Variations of known work prompted by design incentives or other market forces if the variations would have been predictable.* This rationale requires a finding that there were design incentives or other market forces prompting a variation of the known product, as well as a finding that the variation would have been predictable. For the reasons discussed immediately above under section E, there were no design incentives prompting one to modify existing *Treponema* and non-*Treponema* assays. Although Applicants' invention is a superior design, the design incentives were for separate assays due to the biochemistry of the antigens and differing reagents and storage requirements. Moreover, for the reasons discussed above in section A, the Office has not provided any evidence to support a factual assumption of predictability.

(G) *A teaching, suggestion or motivation in the prior art that would have led one to modify the prior art reference or combine the prior art teachings to arrive at the claimed invention.* This rationale requires a finding of a teaching, suggestion, or motivation in the prior art, as well as a finding of reasonable expectation of success. For the reasons discussed immediately above under section E, there was no teaching, suggestion or motivation to modify the *Treponema*-specific and non-*Treponema* assays of the prior art. Moreover for the reasons discussed above in section A, the Office has not provided any evidence to support a factual assumption of reasonable expectation of success.

The cited art fails to teach or suggest a single carrier comprising *both* cardiolipin *and Treponema*-specific antigen on a *single* carrier that is *suitable for diagnosing a Treponema infection*. The ordinary skilled artisan would not have predicted that a single

carrier comprising both cardiolipin and Treponemal protein-based antigens could selectively detect anti-cardiolipin antibodies and anti-*Treponema* protein antibodies with the sensitivity required to diagnose *Treponema* infection. In addition, the ordinary skilled worker would not be motivated to combine cardiolipin and a Treponemal protein-based antigen on a single carrier to detect *Treponema* infection because of the fundamental differences in the antigens. Accordingly, the rationales articulated in *KSR International Co. v. Teleflex Inc.* cannot be used to support a conclusion that the claim would have been obvious. 72 Fed. Reg. at 57529 ("If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art."). The Office has presented no alternative rationale supporting its position. Accordingly, the rejection should be withdrawn.

V. The Rejection under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn.

The Office rejected claim 21 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for lacking antecedent basis. The rejection is moot in view of the amendment to claim 21.

VI. Request for Rejoinder

Claims 14-18 and 20, directed to a method of using the carrier of claim 1, have been withdrawn for being directed to a non-elected invention. Current Patent Office practice permits rejoinder of dependent method claims when parent product claims are deemed allowable. M.P.E.P. § 821.04. Applicants respectfully request that the propriety of the restriction requirement be reconsidered when the claims elected for further prosecution are in condition for allowance, at which time the restriction requirement should be withdrawn and claims 14-18 and 20 examined on the merits.

VII. Conclusion

The application is considered to be in good and proper form for allowance, and the examiner is respectfully requested to pass this application to issue. The Examiner is invited to contact the undersigned attorney by telephone if there are issues or questions that might be efficiently resolved in that manner.

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Respectfully submitted,

By _____

Heather R. Kissling
Registration No.: 45,790
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant